



## Ethics in Public Health Research

### Protecting Human Subjects: the Role of Community Advisory Boards

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Increasingly, researchers grapple with meaningful efforts to involve communities in research, recognizing that communities are distinct from individuals. We also struggle to ensure that individual participants in research are fully protected.

Community advisory boards (CABs) offer an opportunity to adopt a relationships paradigm that enables researchers to anticipate and address the context in which communities understand risks and benefits, and individuals give consent.

CABs provide a mechanism for community consultation that contributes to protecting communities and fostering meaningful research. Furthermore, CABs can help us to re-create informed consent as a process. It is critical that we conduct research to understand the role of CABs in the informed consent process. (*Am J Public Health*. 2004;94:918–922)

#### THE BELMONT REPORT: ETHICAL

*Guidelines for the Protection of Human Subjects*<sup>1</sup> was born from the fire of controversy over egregious abuses of human subjects. Its principles provide the foundation for contemporary regulations designed for the protection of human subjects. Since the mid-1980s, there has been an in-

creased focus on the participation of groups and communities in the research process, originating from the demand of activists to be heard in the context of AIDS research. New voices and scientific challenges today are increasing the pressure to supplement or reinterpret the principles of the Belmont Report. Gostin<sup>2</sup> expands the application of existing ethical principles of respect, beneficence, and justice to populations and communities, extending to groups the protections now reserved for individuals. Weijer<sup>3</sup> asserts that a fourth ethical principle, “respect for communities,” is necessary to address the increasing vulnerability of groups and to supplement the “atomistic” view of the person epitomized in the Belmont Report. Other scholars also agree that the Belmont framework focuses heavily on individuals. Today, research demands that we consider if not a new principle, a new interpretation of Belmont to account for the ways in which research affects communities.<sup>4,5</sup>

The challenge to expand or revise the human subject protections of the Belmont Report by including community protection and participation as a principle builds on the assumption that new principles or regulations are necessary to include communities in a mean-

ingful partnership. However, to date, the existence of the Belmont principles and regulations governing human subjects research has not fully prevented research abuses nor has it contributed to positive partnerships with communities. Therefore, the solution is not to change principles or regulations alone when in fact a new approach that integrates the relationships paradigm that was advocated by King et al.<sup>6</sup> is necessary. Community advisory boards (CABs) become one meaningful and feasible way to operationalize new protections of communities.

#### WHY DOES THE COMMUNITY NEED TO BE INCLUDED?

Advances in science, technology, and biomedical research push the boundaries of our Belmont principles, stimulating the need for communities to be involved in the informed consent process. Emergency medical research involves the application of experimental procedures or medications to unconscious research subjects with closed head trauma or other life-threatening injuries when their condition demands immediate action, standard procedures are not thought to be effective in that case, and the family is unavailable

to provide consent. Changes in Food and Drug Administration regulations allow waivers of informed consent in such life-threatening emergencies.<sup>7</sup> The rights of unconscious subjects are thought to be accorded a degree of protection through the mechanism of “community consultation” that requires prior consultation (by investigators/the institutional review board) with community representatives, as well as public disclosure to the affected community before and after the research.

Burgeoning genetic research fuels public fears, particularly in communities or social groups that have experienced the brunt of social discrimination in the past. As a result, the concept of potential harm to others emerged from the National Bioethics Advisory Commission’s report *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance*.<sup>8</sup> In recommendation 17, the advisory commission explicitly recognizes that the risk of group harm is distinct from the risk of individual harm. Therefore, the commission calls upon researchers to anticipate and disclose such risks and to consult with community representatives if they believe such risks to be possible. In 2000, The National Institute of General Medical Sciences convened the First Commu-



nity Consultation on the Responsible Collection and Use of Samples for Genetic Research.<sup>9</sup> With a growing concern about the potential for discrimination, stigmatization, and breaches of privacy in genetic research, participants raised key questions about how *community* may be defined in research, what risks and benefits exist for community members in research, and how community members can or should participate in the process of research. Participants echoed the commission's stance that there are ethical issues related to research with communities that are distinctly different from the ethical issues related to research with individuals. Most importantly, the meeting resulted in 10 recommendations for genetic research:

1. Define *community* in appropriate and meaningful ways.
2. Understand the potential benefits and risks of research for communities and community members.
3. Obtain broad community input for all phases of research.
4. Respect communities as full partners in research.
5. Resolve all issues pertaining to tissue samples.
6. Establish appropriate review mechanisms and procedures.
7. Facilitate the return of benefits to communities.
8. Foster education and training in community-based research.
9. Ensure dissemination of accurate information to the media and the public.
10. Provide sufficient funds for research and encourage community–researcher partnerships.<sup>9(p2–3)</sup>

A number of difficult questions remain with respect to community consultation, including who is entitled to speak for a community, who decides the research questions, and, finally, whether a community should have a role in approving a protocol.

Minority communities raise significant concerns about genetics research. In early results from the Genome Technology and Reproduction: Values and Public Policy project at the University of Michigan,<sup>10</sup> researchers described Latino and African American participants as particularly concerned that communities of color would bear the burdens of genetic research without receiving potential benefits of that research. Participants argued for a role for communities in every phase of research, whether through partnership, consultation, or a CAB. This is particularly critical in minority communities where cultural and historical context are particularly relevant, and some form of consultation in the process of informed consent can help ensure that researchers gain an understanding of the social context in which community members assess the risks and benefits of research.<sup>11</sup> The Hispanic/Latino Genetics Consultation Network is a collaborative effort between Redes En Accion, the Baylor College of Medicine, and the National Institutes of Health to “create a forum for Latinos to identify, prioritize and disseminate information on genetics.”<sup>12</sup> Their June 2003 forum brought 75 key opinion leaders together with federal agencies to prioritize research issues from the perspec-

tive of the Latino community, thereby shaping the National Institutes of Health's policies, research, and education.

Calls for changes in the interaction between researcher and community also emerge from community voices, often stimulated by mistrust and fatigue from being the “subject” of research while rarely benefiting from the fruits of research. Kone et al.<sup>13</sup> conducted interviews with community residents in several Seattle neighborhoods in a study of community–researcher relationships. Key lessons from that study include the following: (1) researchers must have a clear understanding of what *community* means to those involved and the respective communities themselves; (2) community members from diverse backgrounds must be involved in the research process; (3) community members want to have an active role, including being trained to conduct research; (4) more researchers from racial and ethnic minority populations are needed; and (5) mechanisms to ensure sharing of power and resources are critical. The authors assert that establishing a CAB and developing a community-based participatory research (CBPR) process are potential means to strengthen researcher–community collaboration.<sup>13</sup>

Finally, a disturbing linguistic dynamic has emerged in research discourse, and this potentially undermines our existing mechanisms for the protection of human subjects. It is increasingly common to hear researchers describe informed consent as a task to be done, speaking of the need “to

consent” the subject. This subtle shift in language exposes a dangerous fault line, raising the question of whether the focus is on informed consent as a product, such as a signed document, or informed consent as a process. “To consent” the subject raises questions about the dynamic of power between researcher and potential subject and challenges our existing principles of autonomy and justice. One key element of informed consent is voluntariness or the absence of a significant controlling influence. However, “consenting someone” implies that voluntariness may be more easily compromised. The extent to which the pressure on researchers to enroll minority participants may interact with this dynamic and contribute to potential breaches of informed consent is unknown, yet troublesome. The evolving language of research requires further vigilance to ensure that individual informed consent is not compromised, opening the door for a role of the community to assist in this process.

## WHERE DO WE GO FROM HERE?

Although the drive to involve communities in the process of research stems from a multitude of factors, investigators accomplish this through a variety of means. Inclusion of new principles, elucidation of community consultation and community consent mechanisms, CBPR, inclusion of community members on institutional review boards, and CABs are possible means to include communities in research. Each model has



specific roles, benefits, and drawbacks (a full elucidation of those is beyond the scope of this article).

Weijer and Emanuel<sup>14</sup> contend that the primary rationale for involving communities is that the community has a right to respect and protection, based on a partnership with the researcher. Therefore, they suggest that several protections can be afforded communities: (1) consultation in protocol development, (2) information disclosure and informed consent at the community level, (3) involvement in all phases of the research, (4) access to data and samples that again would require community consent, and (5) involvement in dissemination and publication of results.

They argue that whether the potential protection takes the form of community consultation or community consent will vary depending on the characteristics of the community.<sup>14</sup> For *community consultation* to occur, the community must have specific characteristics such as a health-related common culture, a group that is representative of the community, some mechanism for collective priority setting, and a communication network. If consultation requires a face-to-face meeting, the community must be geographically localized. Such community consultation would consist of involving community representatives in the planning of the study, informing the community as a whole at the start of the study and throughout its course, consulting with the community on the use of the data, and providing a report of the data to the community.<sup>14</sup> However, they recom-

mend that for *community consent* to be possible, the community also must have a legitimate political authority that can make binding decisions.<sup>14</sup> This approach to community consent is an added protection that still preserves individual autonomy. One example of this model is the ability of some tribal nations with governing bodies to determine tribal participation in research endeavors.

CBPR is a growing approach to the development of an equal partnership between the researcher and the community. Israel et al. write that "community based research is a collaborative approach to research that equitably involves community members, organizational representatives, and researchers in all aspects of the research process."<sup>15(p177)</sup> There are multiple rationales for CBPR, including improving the quality and validity of research, bridging cultural gaps between researchers and communities, increasing trust between researchers and communities, involving marginalized communities, and enhancing the relevance and usefulness of the data.<sup>13,15</sup> Additionally, developing research that is meaningful to the community by addressing its expressed needs is one rationale and benefit of CBPR; certainly, this benefit addresses a common complaint of community members whose perception is that communities rarely benefit directly from research. Explicitly addressing informed consent issues is not generally a rationale for the use of CBPR. Although CBPR lends itself well to some areas of research, it is not applicable to all types of research conducted by public

health and other health professionals. Consequently, CABs provide another strategy for protection of communities in research.

According to Strauss et al.,<sup>16</sup> CABs consist of community members with a common identity, history, symbolism, language, and culture. CABs can play various roles. They can (1) act as a liaison between researchers and community, (2) represent community concerns and culture to researchers, (3) assist in the development of study materials, (4) advocate for the rights of minority research study subjects, and (5) consult with potential study participants to provide recommendations about research study enrollment. Although CABs can certainly help to shape the research questions in ways that may be more salient to the community, their role is not necessarily the joint determination of research questions that is necessary with CBPR. CABs can also play a role in the dissemination of results from a study.

There are multiple models for CABs. One model has been the establishment of a CAB for a specific study; much of the literature existing on CABs focuses on this model. However, another model is the establishment of an institutional CAB that may examine a whole array of research studies. The CAB at the Urban Research Center, Center for Urban Epidemiological Studies in Harlem exists to serve the center in its broader sense, addressing an array of health issues.<sup>17–19</sup> At the Center for Minority Health, Graduate School of Public Health at the University of Pittsburgh, the community research advisory

board is a freestanding advisory board that grapples with studies from investigators across the multiple schools of the health sciences including medicine and public health. In Europe, there are multiple models for CABs.

Strauss et al.<sup>16</sup> view CABs as a potential protection against breaches of individual informed consent as well as serving to improve research when the CAB provides for ongoing dialogue between the researchers and the community. They argued that CABs can play a valid role in the threshold, informational, and consent elements of the informed consent process in such a way as to help ensure informed consent by the individual. A review of existing literature would suggest that CABs most commonly contribute to the informational elements of the informed consent process by seeking and evaluating information from investigators on risks and benefits of participation, disseminating it to the community, and making concrete suggestions on informed consent forms.<sup>17,20,21</sup> The CAB at the Urban Research Center in Harlem includes this statement in its operating principles:

All Urban Research Center research projects will meet current ethical standards and will fully respect the rights of all participants in a culturally sensitive manner, including the rights to be aware of risks and benefits, to give informed consent, and to have the option to withdraw from research at any time without penalty to the participant.<sup>17(p532)</sup>

In order for CABs to prevent ethical lapses and to maintain a role in informed consent, they will require appropriate educa-



tion about human subjects' protections. For example, the community research advisory board at the University of Pittsburgh holds educational sessions on the principles of informed consent, research ethics, the institutional review board process, and perceptions of African Americans about participation in research.

CABs may be one viable means of meeting the recommendation from the Institute of Medicine's report on responsible research, which calls for human subject participant protection programs to "foster communication with the general public, research participants and research staff to assure that the protection process is open and accessible to all interested parties."<sup>22(p64)</sup> In fact, the Institute of Medicine considers "transparency—to ensure open communication and interaction with the local community, research participants, investigators, and other stakeholders in the research enterprise" to be a necessary condition for a sound protection program.<sup>22(p52)</sup> The Institute of Medicine panel goes further to call for adequate protections programs to include access to a "responsible, knowledgeable, neutral third party."<sup>22(p65)</sup> The role of that party—to allow for communication, open consideration of concerns, and addressing problem issues—is certainly congruent with that of a CAB.

### A RESEARCH AGENDA ON CABs AND INFORMED CONSENT

A substantial research agenda is necessary to understand the

potential roles and effectiveness of CABs in the informed consent process. Critical questions include the following:

1. To what extent do CABs have some interaction with institutional review boards? What is the interaction?
2. To what extent have CABs contributed to the review or development of informed consent forms and processes? What education or training was necessary in order for them to address these tasks?
3. To what extent may CABs play a role in other elements of informed consent, including the threshold elements of competence and voluntariness and the actual consent elements of decision to act and authorization?
4. To what extent have CABs fulfilled the obligation for community consultation in emergency research that requires a waiver of informed consent?
5. To what extent have CABs been a resource to study participants when questions about ethical conduct of research arise?
6. Have CABs experienced the need to address potential lapses in protection of human subjects? What were the circumstances and how did they respond?
7. To what extent do CABs help facilitate the evolution of communities that have been historically vulnerable in the research endeavor to communities empowered to participate fully in the informed consent process?

There has been little evaluation of the functioning of CABs in the literature. To fully realize

their potential contribution to the process of informed consent, we must understand more about CABs in general. Research on their functions, the roles of members, barriers and challenges, and interactions with researchers and community is essential.

Although the potential for CABs is great, their success lies in the ability of the researchers and CABs to form a true partnership, enabling their different voices to be heard equally. To do so requires that investigators be willing to develop open communication and to share power and decisionmaking with CAB members. It challenges investigators to incorporate understanding of cultural and social context into their research process. Conversely, for a CAB to be successful, CAB members must represent their community honestly, and they must willingly tackle the need to understand often-complex research studies and protocols. Simply creating a CAB without being truly open to working together may, in fact, further harm relationships with the community, which may rightly perceive the CAB as "window dressing."

### CABs AS A REFLECTION OF A PARADIGM SHIFT

Ultimately, CABs may constitute the feasible means of ensuring a role for communities in research and informed consent, enabling researchers to incorporate the relationships paradigm that King et al.<sup>6</sup> raise as an alternative to a focus on the principalist paradigm from a stricter inter-

pretation of the Belmont Report.<sup>1</sup> They argue that researchers frequently conducted research from what they describe as the principalist paradigm that focuses on "balancing principles of autonomy, beneficence, justice, informed consent and confidentiality; assumes ethical universalism (not moral relativism)—truth (not stories); and maintains an atomistic focus—small frame, centered on individuals."<sup>6(p15)</sup> They go on to state that "the moral principles held to govern research with human subjects remain current and meaningful but make sense only in context. Thus, the ethics of human subjects research may be universal but is at the same time deeply particularized, so that what autonomy or informed consent or confidentiality or even benefit and harm means depends on the circumstances."<sup>23(p213)</sup>

King et al.<sup>6,23</sup> challenge us to expand beyond the synchronic (slice-of-time) "principalist paradigm" of Belmont evident in our system of federal regulations to include a "relationships paradigm." Such a shift in approach would account for both the interactions between subjects and their communities and subject—communities with researchers. Their call for an integration of the principalist paradigm with a relationships paradigm is consistent with the functions and potential roles of CABs. The relationships paradigm recognizes the breadth and depth of relevant relationships between individuals and groups in a community; incorporates the relevant contexts including culture, gender, race/ethnicity, his-





tory, community, place, and others that affects research; acknowledges crosscutting issues and allows wider frames of reference; and adopts what they term as a more “narrative focus.”<sup>6</sup>

The relationships paradigm calls for a broader understanding of time beyond that of a specific research study and recognizes that issues of importance in the context of broader community life, occurring both before and after a specific research study, necessitate some continuity of relationship between investigator and community.<sup>6,23</sup> Not infrequently, investigators may enter a community without full comprehension of relevant issues and previous research demands and depart when their grant draws to a close. Adopting a relationships paradigm requires consideration of a longer window of time in the community’s life and the investigator’s roles within the community’s particular context. Beyond the issue of informed consent, CABs provide an avenue to raise questions of particular salience to the community and to share the results of the research with the community, a frequent source of anger for communities that lament the failure of investigators to disseminate their results.

Adopting a new principle of “respect for communities” to expand our existing Belmont principles provides no guarantee that we will conduct research in a manner that fully respects communities. However, CABs offer one opportunity to adopt a relationships paradigm that enables researchers to anticipate and ad-

dress the context in which communities understand risks and benefits and individuals give consent. CABs provide the mechanism for community consultation that contributes to protecting communities and fostering meaningful research. Furthermore, CABs can enable us to fully interpret the principles of autonomy, beneficence, and justice and re-create informed consent as a process. To reap these benefits from CABs, investigators must truly believe them to be of significant value in the research process and create meaningful partnerships with communities. Ultimately, the health of our communities will be the beneficiaries. ■

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